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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/559,599 | 12/02/2005 | Athol Gillies Turner | 048501/303751 | 1531 |
| 826 | 7590 | 11/21/2007 | EXAMINER | |
| ALSTON & BIRD LLP | | | CLARK, AMY LYNN | |
| BANK OF AMERICA PLAZA | | | ART UNIT | PAPER NUMBER |
| 101 SOUTH TRYON STREET, SUITE 4000 | | | 1655 | |
| CHARLOTTE, NC 28280-4000 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 11/21/2007 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|-----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/559,599 | TURNER, ATHOL GILLIES | |
| | Examiner | Art Unit | |
| | Amy L. Clark | 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 August 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,6,8 and 10-25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3,5,7 and 9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 December 2005 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/02/2005.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, and specie A 1, 3, 5, 7 and 9 in the reply filed on 14 August 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-25 are currently pending.

Claims 2, 4, 6 and 10-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 14 August 2007.

Claims 1, 3, 5, 7 and 9 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) was submitted on 2 December 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 1-4 are the only drawings referred to in the specification. Drawings

5/20-20/20 are not described in the specification at all; therefore, it is unclear as to what these drawings are meant to correlate. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: please correct "sterilising" to read sterilizing, please correct "recognised" in line 30 of page 1 to read recognized, please correct "litre" to read liter (See page 12, lines 19 and 30, for example), please correct the ratios from "1/1 or 1/2" to read 1:1 or 1:2 (See page 6, line 12 and page 13, line 5, for examples). Please note that the Examiner has not pointed out all instances where these corrections should be made. Applicant is required to correct all instances where the following words, amounts and phrases appear throughout the specification.

The use of the trademark "V8" (See page 10, line 16), among others (please note that Applicant has provided several trademarks in Applicant's examples towards the end of Applicant's specification, but has sufficiently provided a description for those appearing later on), has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

Claim 1, line 8 and claim 5, line 2 are objected to because of the following informalities: please amend "metabolised" to read metabolized. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the period of incubation" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5, lines 1 and 2 and claim 7, lines 1 and 2 recites the limitation "wherein in step c.) the lipid substrate". There is insufficient antecedent basis for this limitation in the claim because step c.) does not recite a lipid substrate. It appears that Applicant is referring either to the preamble of the claim or step a.).

Claim 5 recites the limitation "said metabolized/transformed inoculated lipid substrate" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "said inoculated substrate mixture" in line 3. There is insufficient antecedent basis for this limitation in the claim since this claim is referring to an incubated mixture, since the limitation recited in this claim refers to step c.).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Stredansky et al. (U, "γ-Linolenic acid production with *Thamnidium elegans* by solid-state fermentation on apple pomace". *Bioresource Technology*, Vol. 73 (2000) 41-45).

Stredansky teaches a solid-state process for obtaining high value fungal oil from apple pomace and spent malt grains, wherein the oil contains biologically active γ-

linolenic acid. Stredansky further teaches that the γ -linolenic acid is obtained by filling flasks with apple pomace impregnated with a nutrient solution containing yeast extract and further adding spent malt grains. Stredansky further teaches that static cultivation was performed at 24 °C in a humidified (near 100%) atmosphere for 8 days after inoculating spore suspension into each flask, which reads on steps a) and b). Stredansky further teaches extraction of lipid and determination of fatty acids by drying the fermented mass, weighing and milling, wherein the lipid fraction is extracted with chloroform/methanol (See page 42, "Solid substrate preparation and cultivation"), which reads on step c) and claim 7.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stredansky et al. (U, " γ -Linolenic acid production with *Thamnidium elegans* by solid-state fermentation on apple pomace". *Bioresource Technology*, Vol. 73 (2000) 41-45), in view of Hamm (V, "Extraction of Lipids." In: Lo, T.C., Baird, M. H. U and Hanson, C., *Handbook of Solvent Extraction* (New York, John Wiley & Sons, 1983), pp. 593-595. TP156.E8H26).

The teachings of Stredansky are set forth above and applied as before.

Stredansky does not teach a temperature between 5 and 20 °C, nor does Stredansky teach solvent extraction of biologically active oil using methanol at a low temperature. However, Hamm teaches that Rigamonti and co-workers published data on the use of methanol and ethanol to extract fatty acids from triglyceride-fatty acid mixtures, in particular, they studied the use of anhydrous and aqueous methanol and showed that at a solvent temperature of 20 °C, the lipid and solvent are miscible (See page 594, column 2, paragraph 2).

Therefore, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method taught by Stedansky to provide the instantly claimed invention because at the time the invention was made, a solid-state process for obtaining high value fungal oil from apple pomace and spent malt grains, wherein the oil contains biologically active γ -linolenic acid was known in the art, as clearly taught by Stedansky, as was that a suitable solvent and solvent temperature to obtain lipids from a composition is 20 °C, as clearly taught by Hamm.

The result-effective adjustment of particular conventional working conditions (e.g., adjusting the type and temperature of solvent used to perform an extraction) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 3, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Floetenmeyer et al. (W, "Continuous culture fermentation of whey permeate to produce microbial oil", J. Dairy Sci, Vol. 68 (1985) 633-637), in view of Steinkraus (X, "Solid-State (Solid-Substrate) Food/Beverage Fermentation Involving Fungi", Vol. 4, No. 2 (1984) 83-88), Hamm (V, "Extraction of Lipids." In: Lo, T.C., Baird, M. H. U and Hanson, C., *Handbook of Solvent Extraction* (New York, John Wiley & Sons, 1983), pp. 593-595. TP156.E8H26) and <http://www.cyberlipid.org/extract/extr0001.htm> (U1)

Floetenmeyer teaches a method of continuous culture fermentation of whey permeate, which reads on an animal derived lipid substrate, to produce microbial oil, wherein the fermentation conditions were run at 30 °C for 18 hours with an aeration rate of 1 vol/vol/min and an agitation rate of 500 to 600 rpm and wherein the oil-accumulating yeast, *Candida curvata* D, was used. Floetenmeyer further teaches that the optimum amount of lipid is produced in 72 hours in a batch fermentation of whey permeate (See page 633 and 644). Floetenmeyer does not teach a solid-state substrate nor does Floetenmeyer teach a relative humidity of between 75-100% or 80-

100%, nor does Floetenmeyer teach that the substrate is incubated for a period of 7-120 days or between 7 and 120 days. However, it would have been obvious to modify the invention taught by Floetenmeyer to provide the instantly claimed invention because Steinkraus teaches that solid substrate (solid state) fermentation is a very useful fermentation method and that it has certain advantages over liquid submerged fermentation (See summary and page 87, last paragraph). Steinkraus further teaches that most yeasts will not grow below an a_w (water activity) of 0.88 (please note that in a closed system the a_w is the measured relative humidity divided by 100, which means that most yeasts will not grow below a measured relative humidity of 88%). Steinkraus further teaches that oxygen is supplied by diffusion among the substrate particles but that forced aeration by humidified air is possible. Steinkraus further teaches that although it is harder to maintain a constant temperature within a solid state fermentation, that on a small scale the temperature can be controlled by limiting the physical dimensions of the fermentation chambers and the substrate mass (See page 86, first paragraph).

Floetenmeyer does not teach that the lipid layer is extracted with methanol at low temperature or a concentrated extract, however Hamm teaches that Rigamonti and co-workers published data on the use of methanol and ethanol to extract fatty acids from triglyceride-fatty acid mixtures, in particular, they studied the use of anhydrous and aqueous methanol and showed that at a solvent temperature of 20 °C, the lipid and solvent are miscible (See page 594, column 2, paragraph 2).

<http://www.cyberlipid.org/extract/extr0001.htm> teaches that alcohols are good solvents

for most lipids (See page 3), that when a large amount of solvent must be evaporated, that it should be done with a rotary film evaporator (concentrated under reduced pressure) at a temperature of no more than 50 °C (See page 6) and that lipids should not be left for any time in the dry state but should be taken up rapidly in an inert non-alcoholic solvent, such as chloroform (See page 7).

Therefore, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method taught by Floetenmeyer to provide the instantly claimed invention because at the time the invention was made, a method of continuous culture fermentation of whey permeate, which reads on an animal derived lipid substrate, to produce microbial oil, wherein the fermentation conditions were run at 30 °C for 18 hours with an aeration rate of 1 vol/vol/min and an agitation rate of 500 to 600 rpm and wherein the oil-accumulating yeast, *Candida curvata* D, was used. Floetenmeyer further teaches that the optimum amount of lipid is produced in 72 hours in a batch fermentation of whey permeate, as clearly taught by Floetenmeyer, and since it was known that solid substrate (solid state) fermentation is a very useful fermentation method and that it has certain advantages over liquid submerged fermentation and that most yeasts will not grow below an a_w (water activity) of 0.88 (please note that in a closed system the a_w is the measured relative humidity divided by 100, which means that most yeasts will not grow below a measured relative humidity of 88%), that oxygen is supplied by diffusion among the substrate particles but that forced aeration by humidified air is possible and that on a small scale the temperature can be

controlled by limiting the physical dimensions of the fermentation chambers and the substrate mass, as clearly taught by Steinkraus, that lipids are easily extractable in methanol at low temperatures and that lipids are not stable for long periods of time in alcoholic solvent, as taught by Hamm, so evaporation to remove solvent is an acceptable step to provide a storable lipid, as taught by

<http://www.cyberlipid.org/extract/extr0001.htm>. Therefore, it would have been obvious to modify the method taught by Floetenmeyer to provide the claimed solid state process in view of Steinkraus, Hamm and <http://www.cyberlipid.org/extract/extr0001.htm>. 's teachings.

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced method because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a suitable amount of incubation time, a suitable humidity, a suitable temperature to obtain the desired product, a suitable solvent system and a suitable method of concentrating a solvent as a result of the methods taught by both Floetenmeyer, Steinkraus, Hamm and <http://www.cyberlipid.org/extract/extr0001.htm>. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
October 19, 2007

Michele C. Flood
MICHELE FLOOD
PRIMARY EXAMINER